2018 Current Fiscal Year Report: National Cancer Institute Clinical Trials and Translational Research Advisory Committee

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1. Department or Agency	2. Fiscal Year
Department of Health and Human Services	2018

3. Committee or Subcommittee	3b. GSA Committee No.
National Cancer Institute Clinical Trials and Translational Research Advisory Committee	29125

4. Is this New During Fiscal Year?	5. Current Charter	6. Expected Renewal Date	7. Expected Term Date
No	04/14/2018	04/14/2020	

8a. Was Terminated During FiscalYear?	8b. Specific Termination Authority	8c. Actual Term Date
No		

9. Agency Recommendation for Next FiscalYear	10a. Legislation Req to Terminate?	10b. Legislation Pending?
Continue	Not Applicable	Not Applicable

11. Establishment Authority Authorized by Law

12. Specific Establishment Authority	13. Effective Date	14. Commitee Type	14c. Presidential?
42 USC 285a-2(b)(7)	11/20/1985	Continuing	No

15. Description of Committee Scientific Technical Program Advisory Board

16a. Total Number of Reports 1

16b. Report Date	Report Title
11/01/2017	Report of the Clinical Trials Informatics Working Group (CTIWG) of the NCI CTAC on Recommendations for the Clinical Trials Reporting Program (CTRP)

Number of Committee Reports Listed: 1

17a. Open 3 **17b. Closed** 0 **17c. Partially Closed** 0 **Other Activities** 0 **17d. Total** 3

Meetings and Dates

Purpose	Start	End
Program Advisory and/or Policy	11/01/2017	- 11/01/2017
Program Advisory and/or Policy	03/07/2018	- 03/07/2018
Program Advisory and/or Policy	07/11/2018	- 07/11/2018

Number of Committee Meetings Listed: 3

	Current FY	Next FY
18a(1). Personnel Pmts to Non-Federal Members	$8,200.00	$8,200.00
18a(2). Personnel Pmts to Federal Members	$0.00	$0.00

18a(3). Personnel Pmts to Federal Staff	$96,391.00	$98,223.00
18a(4). Personnel Pmts to Non-Member Consultants	$4,000.00	$4,000.00
18b(1). Travel and Per Diem to Non-Federal Members	$20,061.00	$20,312.00
18b(2). Travel and Per Diem to Federal Members	$0.00	$0.00
18b(3). Travel and Per Diem to Federal Staff	$0.00	$0.00
18b(4). Travel and Per Diem to Non-member Consultants	$10,397.00	$10,526.00
18c. Other(rents,user charges, graphics, printing, mail, etc.)	$71,644.00	$73,077.00
18d. Total	$210,693.00	$214,338.00
19. Federal Staff Support Years (FTE)	0.60	0.60

20a. How does the Committee accomplish its purpose?

The Committee is composed of scientific leaders and public members knowledgeable in the fields of community oncology, surgical oncology, medical oncology, radiation oncology, patient advocacy, extramural clinical investigation, regulatory agencies, pharmaceutical industry, public health, clinical trials design, management and evaluation, drug development and developmental therapeutics, cancer education, cancer information services, community outreach, vaccine development, cellular oncology, molecular oncology, pediatric oncology, clinical, basic and translational research, cancer center administration, cancer biology and diagnosis, cancer epidemiology, chemotherapy, oncology health care providers, pharmacology, pathology, biostatistics, quality of life, health care outcomes, pain management, cancer treatment and restorative care, and education of health professionals. The Committee provides advice to the Director, NCI, NCI Deputy Directors, and the Director of each NCI Division on the NCI-supported national clinical trials enterprise to build a strong scientific infrastructure by bringing together a broadly developed and engaged coalition of stakeholders involved in the clinical trials process. In FY2018, the Committee met three times. Committee discussions and reports included a wide variety of topics related to reducing barriers, stewardship policies, accrual performance, and adverse event reporting in clinical trials. The committee provided advice on several initiatives and activities including the NCI Community Oncology Research Program (NCORP), the Cancer Immune Monitoring Analysis Centers (CIMAC), the NCI-VA Interagency Group to Accelerate Trials Enrollment (NAVIGATE), the Quantitative Imaging Network (QIN), the Experimental Therapeutics Clinical Trials Network (ETCTN), the ETCTN Drug Development Project Teams, the Investigational Drug Steering Committee, and the Pediatric Early Phase Clinical Trials Network. The Committee deliberated on and approved a report from the CTAC Clinical Trials Informatics Working Group (CTIWG) which provided recommendations for the Clinical Trials Reporting Program (CTRP). The CTAC meeting summaries from the July and November 2017 meetings and the March 2018 meeting were approved by the Committee members during FY2018.

20b. How does the Committee balance its membership?

The Committee consists of up to 25 members. When necessary, five members will hold concurrent membership on either the National Cancer Advisory Board, Board of Scientific Advisors, Board of Scientific Counselors (Basic Sciences and Clinical Sciences and Epidemiology), or NCI Council of Research Advocates. Members are leaders knowledgeable in the fields of community oncology, surgical oncology, medical oncology, radiation oncology, patient advocacy, extramural clinical investigation, regulatory agencies, pharmaceutical industry, public health, clinical trials design, management and evaluation, drug development and developmental therapeutics, cancer education, cancer information services, community outreach, vaccine development, cellular oncology, molecular oncology, pediatric oncology, clinical, basic and translational research, cancer center administration, cancer biology and diagnosis, cancer epidemiology, chemotherapy, oncology health care providers, pharmacology, pathology, biostatistics, quality of life, health care outcomes, pain management, cancer treatment and restorative care, and education of health professionals.

20c. How frequent and relevant are the Committee Meetings?

The Committee meets approximately three times each fiscal year. In FY2018, the Committee met three times. The Committee's deliberations are an indispensable part of the review of a very large clinical trials and translational research program. Additionally, the CTAC Clinical Trials Informatics Working Group (CTIWG) met on October 4, 2017 and the CTAC ad hoc Working Group on Glioblastoma met on August 20, 2018.

20d. Why can't the advice or information this committee provides be obtained elsewhere?

This Committee is composed of recognized biomedical research authorities from outside the NIH in order to secure unbiased and objective evaluations of clinical trials and translational research programs. Their recommendations are invaluable because the complex nature of the research requires a unique balance and breadth of expertise not available at NIH or from other established sources.

20e. Why is it necessary to close and/or partially closed committee meetings?

N/A

21. Remarks

Members: The terms for David Arons, Edith Mitchell, Nikihl Munshi, Louis Weiner and Augusto Ochoa have changed due to administrative extensions. Susan Blaney's term ended on 11/04/2017. As such, their term of service end date is different than what was

reported on the FY17 ACR. Costs: The reduction in operating costs for FY18 is due to a change in how the logistical contractor accounts for labor costs. As such, the logistical contract costs are lower than what was reported on the FY17 ACR. The DFO and Committee Decision Maker positions are held by the same individual because of the assignment of responsibilities within the Institute.

Designated Federal Officer

SHEILA A. PRINDIVILLE DIRECTOR, COORDINATING CENTER FOR CLINICAL TRIALS

Committee Members	Start	End	Occupation	Member Designation
ARONS, DAVID	12/17/2014	09/30/2018	CHIEF EXECUTIVE OFFICER	Special Government Employee (SGE) Member
BARTON, DEBRA	11/12/2017	07/31/2021	MARY LOU WILLARD FRENCH PROFESSOR OF ONCOLOGY NURSING	Special Government Employee (SGE) Member
BLANEY, SUSAN	07/12/2015	11/04/2017	VICE PRESIDENT FOR CLINICAL AND TRANSLATIONAL RESEARCH	Special Government Employee (SGE) Member
CURRAN, WALTER	11/29/2015	07/31/2019	EXECUTIVE DIRECTOR	Special Government Employee (SGE) Member
DAHUT, WILLIAM	05/13/2016	06/30/2020	SCIENTIFIC DIRECTOR FOR CLINICAL RESEARCH	Ex Officio Member
DAVIDSON, NANCY	04/22/2012	10/31/2018	SENIOR VICE PRESIDENT, DIRECTOR AND FULL MEMBER	Special Government Employee (SGE) Member
DOROSHOW, JAMES	07/01/2015	06/30/2020	DEPUTY DIRECTOR	Ex Officio Member
EBERLEIN, TIMOTHY	11/12/2017	07/31/2020	BIXBY PROFESSOR AND CHAIRMAN	Special Government Employee (SGE) Member
FINGERT, HOWARD	11/12/2017	07/31/2020	SENIOR MEDICAL DIRECTOR	Special Government Employee (SGE) Member
GERSHENSON, DAVID	04/18/2016	07/31/2020	PROFESSOR OF GYNECOLOGY	Special Government Employee (SGE) Member
GODLEY, PAUL	11/12/2017	07/30/2021	VICE DEAN FOR DIVERSITY AND INCLUSION	Special Government Employee (SGE) Member
GRAY, PAULETTE	01/11/2007	06/30/2020	DIRECTOR	Ex Officio Member
HAKIM, ROSEMARIE	08/31/2009	06/30/2020	EPIDEMIOLOGIST	Ex Officio Member
KELLEY, MICHAEL	03/11/2009	06/30/2020	NATIONAL PROGRAM DIRECTOR FOR ONCOLOGY	Ex Officio Member
KERLAVAGE, ANTHONY	08/22/2017	06/30/2020	ACTING DIRECTOR, CENTER FOR BIOMEDICAL INFORMATICS AND INFORMATION TECHNOLOGY	Ex Officio Member
LANGEVIN, ANNE-MARIE	10/15/2017	07/31/2021	GREEHEY DISTINGUISHED CHAIR IN PEDIATRIC ONCOLOGY	Special Government Employee (SGE) Member
LEBLANC, MICHAEL	04/19/2015	07/31/2019	MEMBER AND RESEARCH PROFESSOR	Special Government Employee (SGE) Member
LOEHRER, PATRICK	03/06/2016	07/31/2020	DIRECTOR, MELVIN AND BREN SIMON CANCER CENTER	Special Government Employee (SGE) Member
MANKOFF, DAVID	05/31/2015	07/31/2019	GERD MUEHLLEHNER PROFESSOR OF RADIOLOGY	Special Government Employee (SGE) Member
MATRISIAN, LYNN	11/12/2017	07/31/2021	CHIEF RESEARCH OFFICER	Special Government Employee (SGE) Member
MEROPOL, NEAL	11/12/2017	07/31/2021	ASSOCIATE DIRECTOR AND PROFESSOR	Special Government Employee (SGE) Member
MITCHELL, EDITH	03/10/2013	10/31/2018	ASSOCIATE DIRECTOR FOR DIVERSITY AND MINORITY PROGRAMS	Special Government Employee (SGE) Member

MUNSHI, NIKHIL	03/10/2013	10/31/2018	ASSOCIATE DIRECTOR	Special Government Employee (SGE) Member
OCHOA, AUGUSTO	05/31/2016	10/31/2018	DIRECTOR, STANLEY S. SCOTT CANCER CENTER	Special Government Employee (SGE) Member
PAZDUR, RICHARD	12/05/2006	06/30/2020	DIRECTOR, ONCOLOGY CENTER OF EXCELLENCE	Ex Officio Member
PEREZ-SOLER, ROMAN	12/05/2016	07/31/2020	CHAIRMAN	Special Government Employee (SGE) Member
PETERSEN, GLORIA	05/31/2016	07/31/2020	DEPUTY DIRECTOR, MAYO CLINIC CANCER CENTER	Special Government Employee (SGE) Member
ROSEN, STEVEN	11/12/2017	07/31/2021	PROVOST AND CHIEF SCIENTIFIC OFFICER	Special Government Employee (SGE) Member
THEODORESCU, DAN	10/29/2017	07/31/2020	DIRECTOR AND PROFESSOR	Special Government Employee (SGE) Member
WEINER, LOUIS	09/24/2014	07/31/2018	DIRECTOR, LOMBARDI COMPREHENSIVE CANCER CENTER	Special Government Employee (SGE) Member

Number of Committee Members Listed: 30

Narrative Description

The goal of the NIH research is to acquire new knowledge to help prevent, detect, diagnose, and treat disease and disability, from the rarest genetic disorder to the common cold. The NIH works toward that mission by utilizing the National Cancer Institute Clinical Trials and Translational Research Advisory Committee (CTAC). The CTAC conducts and provides oversight and implementation of clinical trials across the Institute. The Committee consists of up to 25 members. When necessary, five members will hold concurrent membership on either the National Cancer Advisory Board, Board of Scientific Advisors, Board of Scientific Counselors (Basic Sciences and Clinical Sciences and Epidemiology), or NCI Council of Research Advocates. Members will be authorities in the fields of community oncology, surgical oncology, medical oncology, radiation oncology, patient advocacy, extramural clinical investigation, regulatory agencies, pharmaceutical industry, public health, clinical trials design, management and evaluation, drug development and developmental therapeutics, cancer education, cancer information services, community outreach, vaccine development, cellular oncology, molecular oncology, pediatric oncology, clinical, basic and translational research, cancer center administration, cancer biology and diagnosis, cancer epidemiology, chemotherapy, oncology health care providers, pharmacology, pathology, biostatistics, quality of life, health care outcomes, pain management, cancer treatment and restorative care, and education of health professionals.

What are the most significant program outcomes associated with this committee?

	Checked if Applies
Improvements to health or safety	✓
Trust in government	

Major policy changes	☑
Advance in scientific research	☑
Effective grant making	☐
Improved service delivery	☐
Increased customer satisfaction	☐
Implementation of laws or regulatory requirements	☐
Other	☐

Outcome Comments

N/A

What are the cost savings associated with this committee?

	Checked if Applies
None	☐
Unable to Determine	☑
Under $100,000	☐
$100,000 - $500,000	☐
$500,001 - $1,000,000	☐
$1,000,001 - $5,000,000	☐
$5,000,001 - $10,000,000	☐
Over $10,000,000	☐
Cost Savings Other	☐

Cost Savings Comments

NIH-supported basic and clinical research accomplishments often take many years to unfold into new diagnostic tests and new ways to treat and prevent diseases.

What is the approximate Number of recommendations produced by this committee for the life of the committee?

73

Number of Recommendations Comments

(69) A motion carried to accept the report of the Clinical Trials Informatics Working Group; (70) A motion carried to approve the minutes of the July 12, 2017, CTAC meting; (71) A motion carried to approve the minutes of the November 1, 2017, CTAC meeting; (72) A motion carried to approve the formation of the Translational Research Strategy Subcommittee; (73) A motion carried to approve the minutes of the March 7, 2018, CTAC meeting.

What is the approximate Percentage of these recommendations that have been or will be Fully implemented by the agency?
99%

% of Recommendations Fully Implemented Comments
The percentage of recommendations implemented stated above was developed at the time the Annual Comprehensive Review report was prepared. Additional information is available through the RePORT (Research Portfolio Online Reporting Tool) website. RePORT provides access to reports, data, and analyses of NIH research activities that advance the mission of the NIH, including information on NIH expenditures, strategic plans, reports on NIH funding, and reports on the organization and people involved in NIH research and research training. The RePORT website is located at http://report.nih.gov.

What is the approximate Percentage of these recommendations that have been or will be Partially implemented by the agency?
0%

% of Recommendations Partially Implemented Comments
The percentage of recommendations implemented stated above was developed at the time the Annual Comprehensive Review report was prepared. Additional information is available through the RePORT (Research Portfolio Online Reporting Tool) website. RePORT provides access to reports, data, and analyses of NIH research activities that advance the mission of the NIH, including information on NIH expenditures, strategic plans, reports on NIH funding, and reports on the organization and people involved in NIH research and research training. The RePORT website is located at http://report.nih.gov.

Does the agency provide the committee with feedback regarding actions taken to implement recommendations or advice offered?
Yes ☑ No ☐ Not Applicable ☐

Agency Feedback Comments
The agency provided feedback to the various NCI advisory boards with periodic updates at meetings.

What other actions has the agency taken as a result of the committee's advice or recommendation?

	Checked if Applies
Reorganized Priorities	☑
Reallocated resources	☐

Issued new regulation	☐
Proposed legislation	☐
Approved grants or other payments	☐
Other	✓

Action Comments

The committee makes recommendations to federal staff on the NCI-supported national clinical trials enterprise to build a strong scientific infrastructure by bringing together a broadly developed and engaged coalition of stakeholders involved in the clinical trials process. Based on the recommendations of this committee, NCI has restructured its clinical trials infrastructure to enhance efficiency and scientific quality, instituted policy changes, developed scientific frameworks for recalcitrant cancers, and constituted oversight working groups.

Is the Committee engaged in the review of applications for grants?

No

Grant Review Comments

N/A

How is access provided to the information for the Committee's documentation?

	Checked if Applies
Contact DFO	✓
Online Agency Web Site	✓
Online Committee Web Site	✓
Online GSA FACA Web Site	✓
Publications	✓
Other	✓

Access Comments

Information on CTAC can be found at the NCI Division of Extramural Activities: Advisory Boards, Committees and Review Groups website at http://deainfo.nci.nih.gov/advisory/ctac/ctac.htm. Each NCI committee’s charter, minutes, agenda, roster, future meeting dates, meeting Power Points and reports are located here. Additionally, the public may view the CTAC meetings (both live and on demand) via the NIH Videocast at the following website: http://videocast.nih.gov/.